UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P.; **THE P.F. LABORATORIES, INC.;** **PURDUE PHARMACEUTICALS, L.P.;** **and RHODES TECHNOLOGIES,** **Plaintiffs,** **v.** **COLLEGIUM PHARMACEUTICAL, INC.,** **Defendant.**	)	**Civil Action No. 15-13099-FDS**

MEMORANDUM AND ORDER ON DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT

SAYLOR, J.

This is a patent dispute concerning a pharmaceutical product: abuse-deterrent, extended-release oxycodone. Plaintiffs Purdue Pharma L.P.; The P.F. Laboratories, Inc.; Purdue Pharmaceuticals L.P.; and Rhodes Technologies (collectively, "Purdue") have brought suit against Collegium Pharmaceutical, Inc. The amended complaint asserts claims for infringement of three related patents pursuant to 35 U.S.C. §§ 271(a), (b), (c), and (e)(2)(A). The patents at issue are U.S. Patent Nos. 9,073,933 ("the '933 patent"), 8,652,497 ("the '497 patent"), and 9,155,717 ("the '717 patent"). The infringement claims arise out of Collegium's filing of a New Drug Application ("NDA") for its abuse-deterrent, extended-release oxycodone products, XTAMPZA ER. On November 21, 2017, the Court issued a Memorandum and Order on Claim Construction, in which it construed five disputed claim terms.

Collegium has moved for summary judgment on three grounds. First, it maintains that the '933 patent is invalid under a theory of issue preclusion, or collateral estoppel. That contention is based on a judgment from the Southern District of New York, affirmed by the Federal Circuit, that three related patents owned by Purdue are invalid. Second, Collegium asserts that even if the '933 patent is valid, it is entitled to judgment of non-infringement as a matter of law because it is not literally infringing and oxycodone myristate (the active ingredient in its product) is not the equivalent of oxycodone hydrochloride (the active ingredient in Purdue's product). Third, it argues that summary judgment of non-infringement of the '497 and '717 patents is appropriate because those patents claim the addition of an "irritant," and its product does not contain an "irritant."

For the following reasons, Collegium's motion for summary judgment will be granted in part and denied in part.

I. Background

Unless otherwise noted, the following facts are undisputed.

A. Factual Background

This dispute concerns pharmaceutical products designed to deter abuse of addictive pain medications, such as oxycodone, as well as methods for reducing potentially toxic impurities in oxycodone pharmaceuticals.

1. Oxycodone Generally

Oxycodone is an opioid. (Pl. SOF ¶ 91). Opioid drugs are used to treat pain, but are also subject to abuse. (Def. SOF ¶ 3; Pl. SOF ¶ 91). Extended-release ("ER") formulations of oxycodone are often prescribed to treat severe pain that requires around-the-clock dosing. (Def. SOF ¶ 2; Pl. Response ¶ 2). ER formulations contain a larger amount of oxycodone than other

dosage forms because the oxycodone is intended to be released over a 12- to 24-hour period. (Def. SOF ¶ 5; Pl. Response ¶ 5). For example, Purdue's original ER OxyContin, which was approved by the U.S. Food and Drug Administration in 1995, was designed to deliver oxycodone over a 12-hour period. (Pl. SOF ¶ 93).

2. Abuse-Deterrent Oxycodone

Unfortunately, the ER formulations of oxycodone are attractive to abusers. To "dose-dump," defeat the ER mechanism, and receive a rapid high, abusers may crush or dissolve the drug and then orally ingest, insufflate (that is, snort), smoke, or inject the drug. (Def. SOF ¶¶ 5–6; Pl. Response ¶¶ 5–6).

As a result, the FDA has placed a high priority on the development of abuse-deterrent opioids. (Def. SOF ¶ 9; Pl. Response ¶ 9). The FDA approved an abuse-deterring version of OxyContin in 2010. (Pl. SOF ¶ 94). That version incorporated two features: (1) a harder tablet, to resist crushing, and (2) a gelling agent, to impede snorting and injecting of any powder resulting from successful crushing. (*Id.*). Those features are the subject of two of the patents at issue (the '497 and '717 patents). In April 2013, the FDA granted abuse-deterrent OxyContin the first abuse-deterrent labeling. (Pl. Response ¶ 8).

Collegium has developed an abuse-deterrent, ER formulation of oxycodone called XTAMPZA ER. (Def. SOF ¶ 14; Pl. Response ¶ 14). Collegium filed an NDA with the FDA for XTAMPZA ER, seeking approval to manufacture and sell the drug. (*See, e.g.*, Def. SOF ¶ 24). That NDA forms the basis of Purdue's First Amended Complaint ("FAC") for patent infringement.

3. Removal of Impurities from Oxycodone

Oxycodone, as manufactured, contains a potentially toxic impurity. The impurity is 14-

hydroxycodeinone ("14-hydroxy"), an alpha, beta-unsaturated ketone ("ABUK").

The FDA has been concerned about lowering or eliminating the level of 14-hydroxy for some time. *In re OxyContin Antitrust Litigation*, 994 F. Supp. 2d 367, 385 (S.D.N.Y. 2014). In February 2003, Purdue submitted a supplemental NDA to the FDA. *Id.* In January 2004, the FDA approved the request with several conditions. *Id.* Among those conditions was to either provide evidence that the level of 14-hydroxy in its oxycodone was safe, to lower the level of 14-hydroxy to less than ten parts per million (10 ppm). *Id.*

B. Patents at Issue

1. The '933 Patent

a. Description of the Patent

The '933 patent is entitled "Oxycodone Hydrochloride Having Less Than 25 PPM 14-Hydroxycodeinone." It was issued on July 7, 2015. ('933 patent). Purdue is a named assignee.[1]

The '933 patent claims both a product (an oxycodone composition) and a process for preparing it by removing a source of 14-hydroxy from that product—that is, 8α,14-dihydroxy-7,8-dihydrocodeinone ("8α")—during manufacture. Representative claim 1 recites "An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride and [8α] and less than 25 ppm of [14-hydroxy]." Representative claim 10 recites "A process for preparing an oxycodone hydrochloride composition having less than 25 ppm [14-hydroxy], comprising removing [8α] from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm [14-

[1] The '933 patent names Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors and Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies as the assignees.

hydroxy]."[2]

According to the patent, methods for reducing the amount of 14-hydroxy in an oxycodone hydrochloride composition were known in the prior art. (*Id.* col.1, ll. 47–col. 2 ll. 2). At the time of the patent, existing procedures for reducing toxicity in oxycodone hydrochloride produced levels of 14-hydroxy greater than 100 ppm. (*Id.* col. 2 ll. 12–19).

b. Prosecution History

During prosecution of the '933 patent, an examiner from the United States Patent and Trademark Office ("PTO") rejected all of the claims in Purdue's application on the ground of obviousness-type double patenting. (*See* Def. Ex. 17 at 5–6). The examiner's determination was based on a comparison to Purdue's existing patents, including the low-ABUK patents. The rejection read: "Although the conflicting claims are not identical, they are not patentably distinct from each other because Oxycodone hydrochloride [API] having less than 25 ppm [14-hydroxy] of the cited patent encompasses [the] instant claims." (Def. Ex. 17 at 6).

To avoid the double-patenting rejection, Purdue filed terminal disclaimers on October 1, 2014. (*See* Def. Ex. 18 at 12–13).[3] Purdue noted that it "traverse[d] these rejections" and that "[t]he filing of these terminal disclaimers is neither an admission of the propriety of the rejections nor an admission that the inventions claimed . . . are not 'independent and distinct' from the inventions" of the low-ABUK patents. (Def. Ex. 18 at 13).

The examiner maintained the obviousness rejection of the '933 patent claims in light of

[2] Purdue asserts claims 1-4, 10, 14, 16, and 17 of the '933 patent. Of those claims, six are product claims: independent claims 1 and 16 and dependent claims 2, 3, 4, and 17. As set forth below, independent claim 10 and dependent claim 14 are process claims.

[3] A terminal disclaimer is a way for an applicant to overcome a double-patenting rejection; such a disclaimer limits the enforceability of the new patent to the statutory term of the original patent. *See Quad Envtl. Corp. v. Union Sanitary District*, 946 F.2d 870, 874 (Fed. Cir. 1991).

the prior art. (*See* Pl. Ex. 30 at 6–10). In response, on March 4, 2015, Purdue asserted that the examiner acknowledged that "the existence of [8α] was not known prior to the priority date of the present application," and that therefore "one skilled in the art would not have 'figured out to dehydrate [8α]' as asserted by the Examiner." (Pl. Ex. 30 at 7). On March 23, 2015, after Purdue's response was submitted, the examiner allowed the claims. (*See* Pl. Ex. 31).

2. The '497 Patent

The '497 patent is entitled "Pharmaceutical Formulation Containing Irritant." It was issued on February 18, 2014. ('497 Patent). Purdue Pharma L.P., is the named assignee on the '497 and '717 patents.[4]

The '497 patent is generally directed to "provide an oral dosage form of an opioid analgesic which is subject to less parenteral . . . intranasal . . . [and] oral abuse than other dosage forms." (*Id.* col. 2 ll. 14–22). The patent is also directed to preventing abuse of drugs other than opioid analgesics that may be the subject of abuse. (*Id.* col. 5 ll. 35–40). At the time the patent was issued, a number of other techniques were known for deterring opioid abuse. (*Id.* col. 1 ll. 28–41, 55–67; *id.* col. 1 ll. 1–4). In certain embodiments, the patent provides an opioid product that includes "an aversive agent such as an irritant to discourage from tampering with the dosage form and thereafter inhaling, injecting, or swallowing the tampered dosage form. Preferably, the irritant is released when the dosage form is tampered with and provides a burning or irritating effect to the abuser upon inhalation, injection, and/or swallowing of the tampered dosage form." (*Id.* col. 2 ll. 52–59).

3. The '717 Patent

The '717 patent is entitled "Pharmaceutical Formulation Containing Irritant." It was

[4] Both the '497 patent and the '717 patent name Richard Sackler as the inventor and Purdue Pharma L.P. as the assignee.

issued on October 13, 2015. ('717 Patent). The '717 patent shares a specification with the '497 patent.

C. Previous Litigation Concerning the Same or Similar Patents

1. The *Teva* Litigation

Prior to the filing of this lawsuit, Purdue sued Teva Pharmaceuticals, USA, Inc. in the Southern District of New York, for infringement. Purdue alleged that Teva's generic drugs infringed U.S. Patent Nos. 7,674,799 ("the '799 patent"), 7,647,800 ("the '800 patent"), and 7,683,072 ("the '072 patent") (collectively, "the low-ABUK patents"). Teva argued that the asserted claims of the low-ABUK patents were invalid. *See In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 376 (S.D.N.Y. 2014) ("*Teva*").

On January 14, 2014, after a twenty-day bench trial, Judge Sidney H. Stein issued findings of fact and conclusions of law in a lengthy memorandum decision. *See Teva*, 994 F. Supp. 2d at 376. In substance, Judge Stein found that each of the asserted claims was invalid as obvious in light of the prior art.

Judge Stein reviewed the history of the claimed invention at some length. *Id.* at 384-87. He noted that Purdue had been attempting to find ways to reduce 14-hydroxy levels in its oxycodone since at least 2001. *Id.* at 384. He further noted:

> To manufacture oxycodone, Purdue employed these steps:
>
> > [F]irst, it oxidized thebaine, a derivative of the opium poppy, to form 14-hydroxy; second, [it] hydrogenated the 14-hydroxy to form oxycodone free base; and third, it added hydrochloric acid to form oxycodone hydrochloric salt.

Purdue's initial efforts to reduce 14-hydroxy focused on the second step of the synthesis. *Id.* at 385. Purdue assumed that "the unwanted 14-hydroxy in the end product was merely left-over 14-hydroxy that had not been hydrogenated in [the] second step." *Id.* It attempted to

ensure that the hydrogenation process was complete, and appeared to have eliminated or nearly eliminated all the 14-hydroxy. *Id.* But when it finished the third step—adding hydrochloric acid to form a salt—it tested the product "and found that the 14-hydroxy had returned in vast quantities." *Id.*

After experimentation and analysis, Purdue discovered that the "culprit" was 8α, which transformed into 14-hydroxy during the process. *Id.* at 387. It then developed a dehydration process with two levels of hydrogenation, which permitted the production of oxycodone with 14-hydroxy levels less than 10 ppm. *Id.* The second hydrogenation process occurred after the third step—that is, after the oxycodone free base had been converted to oxycodone hydrochloric salt. *Id.*

In substance, the claims at issue consisted of an oxycodone salt with extremely low levels of 14-hydroxy. *See id.* at 376. Judge Stein found that one significant difference between the prior art and the asserted claims was that "the prior art did not disclose the existence of 8α or teach that it converts to 14-hydroxy." *Teva*, 994 F. Supp. 2d at 397. He observed that "8α was unknown in the prior art: its very existence was unexpected." *Id.* at 401. However, that difference between the low-ABUK patents and the prior art did not save them from being held invalid on obviousness grounds.

Because all of the asserted claims were product-by-process claims, Judge Stein "consider[ed] only the product limitations of [the] claim, not process limitations or source limitations that add no patentable significance to the end product." *Id.* at 403.[5] "As a matter of law, the 8α-derived limitation . . . [was] disregarded as a process limitation" in determining

[5] For example, claim 1 of the '072 patent claimed "[a]n oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm [14-hydroxy], wherein at least a portion of the [14-hydroxy] is derived from [8α]." ('072 patent col. 34 ll. 57–60).

validity. *Id.* at 405. Thus, Judge Stein "assesse[d] the validity of the low-ABUK oxycodone API [that is, active pharmaceutical ingredient] product—and its various purity and oral dosage form limitations—not oxycodone API with 14-hydroxy obtained from 8α." *Id.* at 403.

Judge Stein found that the invention would have been obvious to a person of skill in the art. *Id.* at 403-04. First, he concluded that skilled artisans had a reason to develop low-ABUK oxycodone, principally because the FDA had communicated a desire to reduce such impurities in oxycodone. *Id.* at 404. Second, he concluded that "[f]aced with the problem of excess 14-hydroxy in oxycodone . . . , ordinary skilled artisans would have considered solving the problem by using hydrogenation." *Id.* Third, he concluded that "[i]t would have been 'obvious to try' to use hydrogenation after the salt formation step." *Id.* at 405. Fourth, he concluded that "[t]he patent claims extend to the obvious, even if they could be practiced in a nonobvious way." *Id.* at 406-07. Finally, he concluded that "the secondary considerations do not demonstrate nonobviousness." *Id.* at 407.

As to the third point, Purdue contended that the "recognition of 8α as a source of 14-hydroxy in oxycodone salts permitted the inventors to conclude that the application of a hydrogenation step after a salt formation step would produce low-ABUK oxycodone." *Id.* at 405. Judge Stein disagreed. First, he concluded that the discovery of 8α was "immaterial to the low-ABUK product claimed by the patents." *Id.* That was true as a matter of law (because he disregarded process limitations) and as a matter of fact (because "identification of a source of the 14-hydroxy in the end product does not have any effect on the structure or nature of the end product."). *Id.* Second, he concluded that "8α proved largely irrelevant to the process used by Purdue to obtain the product claimed by the patents," because "the low-ABUK process hinges on hydrogenation—not on 8α." *Id.*

As to the fourth point—that is, his conclusion that the patent claims extend to the obvious, even if they could be practiced in a non-obvious way—Judge Stein observed as follows:

> The Court agrees that with its knowledge of 8α Purdue had the capability to practice its claims in a way that would have been nonobvious. That is, Purdue could practice its claims by tailoring them to 8α. What matters, however, is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103. Instead of claiming 8α directly, Purdue claimed low-ABUK oxycodone API in various forms. Its contribution to the science of that reaction was to identify additional explanations for why known techniques, used for their known purpose, would create the product. Invention requires something more.

Id. at 407 (citations and quotations omitted).

Finally, as to the low-ABUK patents, Judge Stein's opinion concluded:

> The dispute over the low-ABUK patents concerns the line between patentable invention and commendable improvement. The three patents at the center of this dispute describe an improved oxycodone API product containing less of the 14-hydroxy impurity than any oxycodone API available at the time of the invention. This product is an improvement but not an invention. Low-ABUK oxycodone stood within reach of any person of ordinary skill with the desire to use routine science and common sense to improve oxycodone API product.
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> * * *
>
> Purdue holds out 8α as its contribution to the art. And, indeed, identifying 8α was genuine insight. But the evidence overwhelmingly proved that 8α imparts no significance to the structure of 14-hydroxy. It imparts no distinguishing characteristics to oxycodone. And it imparts no significance to the product claimed by the patents. Knowledge of 8α permits a skilled artisan to understand *why* 14-hydroxy reappears in a synthetic scheme with a salting step. But knowledge of 8α does not explain *how* to fix the problem. The solution has everything to do with hydrogenation, and that solution would have been obvious to a person of skill in the art, whether that person knew of 8α or not.
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> In summary, . . . [t]he Court concludes . . . that Teva has demonstrated by clear and convincing evidence that each of the asserted claims is invalid as obvious pursuant to 35 U.S.C. § 103.

Id. at 413.

In 2016, the Federal Circuit affirmed Judge Stein's determination that the asserted claims of the low-ABUK patents were obvious in light of the prior art. *See Purdue Pharma L.P. v. Epic*

Pharma, LLC, 811 F.3d 1345, 1355 (Fed. Cir. 2016) ("*Purdue*").[6]

2. The *Mylan* Litigation

The '933 patent at issue here was also the subject of a patent infringement action in the District of Delaware filed by Purdue against Mylan Pharmaceuticals, Inc. *See Purdue Pharma L.P. v. Mylan Pharmaceuticals, Inc.*, 2017 WL 784989 (D. Del. Mar. 1, 2017). Mylan moved to dismiss the complaint on the basis of collateral estoppel (that is, issue preclusion) in light of Judge Stein's decision in *Teva*. Magistrate Judge Sherry R. Fallon issued a report and recommendation to the district judge recommending that the motion to dismiss be denied.

Magistrate Judge Fallon concluded that "defendants have failed to establish that the invalid claims of the previously-litigated low-ABUK patents are sufficiently identical to the disputed claims of the '933 patent." *Id.* at *5. Specifically, she found that "[t]he claims of the '933 patent contain limitations not set forth in the low-ABUK patents, but whether these limitations are material to the patentability of the '933 patent is a question of fact to be reserved for a later stage of the proceedings." *Id.* She found that there were three such limitations in claims 1 and 16 of the '933 patent: (1) the 8α limitation; (2) the 95% limitation, and (3) (as to claim 16) the 5 ppm codeinone limitation.

First, claims 1 and 16 claim "[a]n oxycodone hydrochloride composition" that "comprises" 8α, among other limitations. *Id.* Magistrate Judge Fallon noted that the low-ABUK patents litigated in *Teva* did not contain such a limitation, and that the "8α limitation present in the '933 patent claims must be evaluated to determine the validity of the claims." *Id.* at *5-6. She rejected the argument that the PTO's double-patenting rejection of the '933 patent, and

[6] The Supreme Court denied the subsequent petition for a writ of certiorari. *See Purdue Pharma L.P. v. Epic Pharma, LLC*, 137 S. Ct. 475, 475 (2016).

Purdue's subsequent terminal disclaimer, required the application of issue preclusion. *Id.* at *6-7. And she rejected the argument that the doctrine of inherency required that the '933 patent be invalidated based on its similarities to the invalid low-ABUK patents. Among other things, she noted that the doctrine applied to prior art references, and that in any event "the inherent teaching of a prior art reference is a question of fact." *Id.* at *7-8.

Second, claims 1 and 16 specify that the composition must comprise at least 95% oxycodone hydrochloride. *Id.* at *8. Magistrate Judge Fallon noted that the invalidated patents contained no such limitation, that "[t]he *Teva* decision does not discuss the percentages of oxycodone in the prior art." *Id.* at *9. She concluded that "[t]herefore, it would be inappropriate at this stage of the proceedings for the court to conclusively rule that the 95% limitation does not materially affect the patentability of the '933 patent." *Id.*

Third, claim 16 contains a limitation that the composition "comprises . . . less than 5 ppm of codeinone." Again, Magistrate Judge Fallon noted that "[t]his limitation was not present in the low-ABUK patent claims," and "codeinone was not discussed in the course of the *Teva* litigation." *Id.* She concluded that the question of whether the limitation "materially alters the patentability of claim 16 is fact-intensive," and therefore declined to hold that *Teva* had a preclusive effect.

Finally, Magistrate Judge Fallon concluded that the patentability of the processes identified in claim 10 of the '933 patent had not been litigated, and therefore were not an appropriate subject for issue preclusion. *Id.*

The Report and Recommendation was subsequently adopted by the District Judge. *Purdue Pharma L.P. v. Mylan Pharmaceuticals, Inc.*, 2017 WL 2569604 (D. Del. June 13, 2017).

D. Collegium's Abuse-Deterrent Formulation, XTAMPZA ER

Collegium has developed an abuse-deterrent, ER formulation of oxycodone called XTAMPZA ER. (Def. SOF ¶ 14; Pl. Response ¶ 14). XTAMPZA ER uses a microsphere-in-capsule platform and was "designed to protect the active pharmaceutical ingredient from immediate release upon attempted manipulation of the formulation." (Def. SOF ¶ 14; Pl. Response ¶ 14). Collegium maintains that XTAMPZA ER's wax matrix of microspheres "imparts extended drug release and provides physical and chemical barriers to manipulation." (Def. SOF ¶ 20).

The microspheres contain myristic acid, yellow beeswax, carnauba wax, stearoyl polyoxyl-32 glycerides, and oxycodone API. (*See id.* ¶ 18; Pl. Response ¶ 18). Collegium appears to contend that the drug substance present in XTAMPZA ER is oxycodone base; Purdue disputes that fact, contending that oxycodone is present in XTAMPZA ER as oxycodone myristate salt. (*See* Def. SOF ¶¶ 18, 66; Pl. Response ¶¶ 18, 66).[7] According to Collegium, oxycodone must be fully dissolved in the wax to form XTAMPZA ER's wax matrix. (Def. SOF ¶ 22). But oxycodone base, on its own, is not soluble in wax. (*Id.*). Myristic acid is capable of dissolving oxycodone base in wax and thus was selected to be used in the microsphere formulation. (*Id.* ¶¶ 23–24).

Two additional companies play roles in XTAMPZA ER's manufacturing process. Collegium purchases oxycodone base from Noramco, Inc. ("Noramco"). (Def. SOF ¶ 54; Pl. Response ¶ 54). Collegium's contract manufacturer, Patheon Pharmaceutical, Inc. ("Patheon"), "combines the Noramco oxycodone base with molten myristic acid and other ingredients and

[7] In its Local Rule 56.1 Reply Statement, Collegium seems to abandon the argument that oxycodone base is the active pharmaceutical ingredient in XTAMPZA ER. (*See* Def. Reply ¶ 134 (agreeing that the active ingredient is oxycodone myristate)).

forms the melt into microspheres." (Def. SOF ¶ 59; Pl. Response ¶¶ 59, 130; Def. Reply ¶ 130).

E. Procedural Background

The Court issued its Memorandum and Order on Claim Construction on November 21, 2017. In that memorandum and order, the Court construed the five claims that were disputed as follows:

(1) "Irritant" in the '497 and '717 patents was construed to mean "a compound that imparts an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention."

(2) "Effective amount of an irritant to impart an irritating sensation" in the '497 patent was construed to mean "an amount of an irritant sufficient to impart an irritating sensation."

(3) "An effective amount of an irritant to impart a burning sensation" in the '717 patent was construed to mean "an amount of an irritant sufficient to impart a burning sensation."

(4) "Effective amount to discourage an abuser from tampering with the dosage form" in the '717 patent was construed to mean "an amount sufficient to reduce the potential that an abuser will tamper with the dosage form."

(5) "Removing 8α, 14-dihydroxy-7,8-dihydrocodeinone" in the '933 patent was construed to mean "the amount of 8α, 14-dihydroxy-7,8-dihydrocodeinone present in the oxycodone base composition is reduced."

(Mem. & Order on Claim Construction at 20–21).

With the claims now construed, the Court may fully consider Collegium's non-infringement arguments in support of summary judgment. *See Absolute Software, Inc. v. Stealth*

Signal, Inc., 659 F.3d 1121, 1129 (Fed. Cir. 2011) (stating that, after claims are construed, "the claim as properly construed must be compared to the accused device or process").

II. Legal Standards

A. Summary Judgment

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. General Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991) (quoting *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990)). Summary judgment shall be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant . . . would permit a rational fact finder to resolve the issue in favor of either party." *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990) (citation omitted). In evaluating a summary judgment motion, the court indulges all reasonable inferences in favor of the nonmoving party. *See O'Connor v. Steeves*, 994 F.2d 905, 907 (1st Cir. 1993). When "a properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (quotations omitted). The nonmoving party may not simply "rest upon mere allegation or denials of his pleading," but instead must "present affirmative evidence." *Id.* at 256–57.

B. Infringement

"Patent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence." *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011).

To prove literal infringement, "a patentee must show that every limitation of the claims asserted to be infringed is found in the accused device." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997). If the accused device does not literally infringe a claim, a patentee may be able to prove infringement under the doctrine of equivalents. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002). The central inquiry in a doctrine of equivalents analysis is whether "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." *Warner-Jenkinson Co.*, 520 U.S. at 40; *accord TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1377 (Fed. Cir. 2008) (explaining that "the 'all elements' rule is applicable to infringement under the doctrine of equivalents just as it is to literal infringement").

One test used to resolve that central inquiry is the function-way-result test. *See, e.g.*, *Siemens Med. Solutions USA, Inc.*, 637 F.3d at 1279. In that test, infringement can be established "by showing on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product." *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1312 (Fed. Cir. 2009).

An accused infringer can be liable for either direct or indirect infringement under the doctrine of equivalents. *See* 35 U.S.C. § 271(a)–(b). Direct infringement "occurs where all steps of a claimed method are performed by or attributable to a single entity." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015). Another entity's actions may be

attributed to an alleged infringer when the alleged infringer "directs or controls others' performance" or "form[s] a joint enterprise" with the entity. *Id.* Direction or control—which is a question of fact—can be established through a contract "to perform one or more steps of a claimed method" between the alleged infringer and the other entity. *Id.* at 1023.

"Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement." *Dynacore Holdings Corp. v. U.S. Phillips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004). Liability under that theory does not apply unless the alleged infringer "knew of the patent and that 'the induced acts constitute patent infringement.'" *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011)). However, willful blindness may satisfy the knowledge requirement implicit in 35 U.S.C. § 271(b). *See Global-Tech Appliances, Inc.*, 563 U.S. at 769 (listing two requirements for willful blindness: (1) subjective belief "that there is a high probability that a fact exists"; and (2) "deliberate actions [taken] to avoid learning of that fact").

Prosecution-history estoppel is an important limit on the scope of claims, including the doctrine of equivalents. *See Festo Corp.*, 535 U.S. at 734 ("Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose."). A doctrine-of-equivalents claim cannot succeed when it concerns "subject matter relinquished when a patent claim is narrowed during prosecution." *Conoco, Inc. v Energy & Envtl. Intern., L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006). There are two ways in which prosecution-history estoppel can occur: (1) through a "narrowing amendment to the claim"; or (2) "by surrendering claim scope through argument to the patent examiner." *Id.* For amendment-based estoppel, the patentee bears the burden of showing that the reason for amending the claim "was unrelated to

patentability." *Id.* Argument-based estoppel is more forgiving to the patentee; to invoke the doctrine, there must be a "clear and unmistakable surrender of subject matter" in the prosecution history. *Id.* at 1364 (quoting *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003). The court will "not presume a patentee's arguments to surrender an entire field of equivalents through simple arguments and explanations to the patent examiner." *Id.* When there are multiple patents in a family, "prosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1333 (Fed. Cir. 2003).

III. Analysis

A. The '933 Patent: Issue Preclusion

Purdue asserts three independent claims from the '933 patent: claims 1, 10, and 16. Relying on *Teva*, which found the asserted claims of the low-ABUK patents invalid, Collegium argues that the '933 patent claims are invalid under a theory of issue preclusion.

The doctrine of issue preclusion, or collateral estoppel, "prevents a party from relitigating issues that have been previously adjudicated." *Rodríguez-García v. Miranda-Marín*, 610 F.3d 756, 770 (1st Cir. 2010). In a patent infringement case, courts must "apply the law of the regional circuit to the general procedural question of whether issue preclusion applies." *Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1314 (Fed. Cir. 2015). But the law of the Federal Circuit governs aspects of an issue-preclusion determination that implicate "substantive issues of patent law." *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (citation omitted). For example, Federal Circuit precedent should resolve the question of "whether a particular claim in a patent case is the same as or separate from another claim." *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335,

1341 n.1 (Fed. Cir. 2012). District courts must also answer questions about the scope of prior Federal Circuit decisions using that court's law. *See Soverain Software LLC*, 778 F.3d at 1314.

In the First Circuit, issue preclusion requires that "(1) the issue sought to be precluded in the later action is the same as that involved in the earlier action; (2) the issue was actually litigated; (3) the issue was determined by a valid and binding final judgment; and (4) the determination of the issue was essential to the judgment." *Rodríguez-García*, 610 F.3d at 770 (quoting *Ramallo Bros. Printing, Inc. v. El Día, Inc.*, 490 F.3d 86, 90 (1st Cir. 2007)).[8] The opposing party also must have had a "full and fair opportunity for judicial resolution of the same issue." *Id.* (quoting *Fiumara v. Fireman's Fund Ins. Cos.*, 746 F.2d 87, 92 (1st Cir. 1984)).

When it comes to patent validity, the unadjudicated claims need not be identical to the adjudicated claims. *See Soverain Software LLC*, 778 F.3d at 1319. Issue preclusion will bar a patentee from relitigating issues as long as "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity." *Ohio Willow Wood Co.*, 735 F.3d at 1342.

Collegium raises two issue-preclusion arguments. First, it contends that the findings of the PTO should result in issue preclusion as a matter of law. Second, it contends that the issues decided by Judge Stein in *Teva* are essentially identical to the issues presented here, and that Purdue is therefore precluded from relitigating those issues. As set forth above, defendant Mylan made similar arguments in the Delaware litigation, which were rejected by the court.

[8] The Federal Circuit's requirements for issue preclusion are similar. *See Jet, Inc. v. Sewage Aeration Sys.*, 223 F.3d 1360, 1366 (Fed. Cir. 2000) (stating that four factors are "(1) identity of the issues in a prior proceeding; (2) the issues were actually litigated; (3) the determination of the issues was necessary to the resulting judgment; and, (4) the party defending against preclusion had a full and fair opportunity to litigate the issues").

1. Whether the PTO Findings Should Have Preclusive Effect

Collegium first contends that the findings of the PTO require the application of the doctrine of issue preclusion. As noted, the PTO rejected all of the claims in the '933 patent application on the ground of obviousness-type double patenting in light of the earlier low-ABUK patents from the same family. (*See* Def. Ex. 17 at 5–6). The examiner stated that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because Oxycodone hydrochloride [API] having less than 25 ppm [14-hydroxy] of the cited patent encompasses instant claims." (Def. Ex. 17 at 6). To overcome the double-patenting rejection, Purdue filed terminal disclaimers. (*See* Def. Ex. 18 at 12–13). Based on that evidence, Collegium asserts that issue preclusion on the question of invalidity is appropriate.

"[U]nlike examination for obviousness based on prior art, the issue of obviousness-type double patenting is directed to whether the invention claimed in a later patent is an obvious variant of the invention claimed in an earlier patent." *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 625 F.3d 719, 722 (Fed. Cir. 2010) (per curiam). Here, the PTO's determination and the terminal disclaimers alone are not sufficient to require issue preclusion as a matter of law. First, Collegium offers no case law to support its assertion that a PTO examiner's rejection should be given controlling weight in an issue-preclusion analysis. (*See* Def. Summ. Judg. Br. at 15–16; Def. Summ. Judg. Reply at 1–2). In fact, at least one court has suggested otherwise. *See Edwards Lifesciences Corp. v. St. Jude Med., Inc.*, 2003 WL 25784357 at *11 n.19 (C.D. Cal. Aug. 29, 2003) (noting that an obviousness-type double-patenting rejection "does not mean that the respective claims are considered the same" as the first-filed claims). Moreover, the obviousness-type double-patenting inquiry only involves a claim-to-claim comparison between the first-filed patent and the later-filed application. *See Quad Envtl. Techs. Corp. v. Union*

Sanitary Dist., 946 F.2d 870, 873–74 (Fed. Cir. 1991). It does not involve a detailed analysis of whether individual claim limitations would materially affect obviousness if they are selectively added to or subtracted from consideration, which is required for the "same issue" element of the issue-preclusion test. *See Ohio Willow Wood Co.*, 735 F.3d at 1342.[9] Finally, even assuming that the examiner's determination does indicate that the '933 patent claims are invalid on obviousness grounds, the remaining elements of the issue-preclusion analysis must still be satisfied before the doctrine is applied. *See Rodríguez-García*, 610 F.3d at 770 (listing issue-preclusion elements in the conjunctive).

The filing of terminal disclaimers "simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection." *Quad Envtl. Techs. Corp.*, 946 F.2d at 874. It would be "improper to convert this simple expedient of 'obviation' into an admission [of obviousness] or acquiescence or estoppel on the merits." *Id.*

In short, this Court agrees with the *Mylan* court that the PTO's rejection and Purdue's subsequent terminal disclaimer do not require a finding of issue preclusion. Each of the asserted claims of the '933 patent must be assessed for issues that could materially alter the validity analysis in *Teva*.

2. Whether the *Teva* Decision Should Have Preclusive Effect

Whether Judge Stein's decision in *Teva* should be given preclusive effect in this matter presents a much closer call. As set forth above, in the *Mylan* case, the District Court in Delaware

[9] The Court also hesitates to attach preclusive power to the PTO's determination because the examiner's decision and an invalidity determination from a federal court have different consequences. When the PTO rejects claims for obviousness-type double patenting, the applicant may file a terminal disclaimer to avoid that rejection and may go on to enforce the patent. *See In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998). But when claims are ruled invalid as obvious by a federal court, the patent owner cannot enforce them against an infringer. *See Teva*, 994 F. Supp. 2d at 437–38.

denied a motion to dismiss that contended that claims 1 and 16 of the '933 patent should be held invalid on the basis of issue preclusion in light of *Teva*. With considerable misgivings, this Court will take a similar approach, and deny the motion for summary judgment here.

a. Claims 1 and 16

The principal question concerns the validity of independent claims 1 and 16 of the '933 patent. Again, claim 1 recites "[a]n oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, [8α], and less than 25 ppm of [14-hydroxy]." Claim 16 is similar, but includes the additional limitation that the composition also comprises "less than 5 ppm of codeinone."

Both claims 1 and 16 are product claims. *See Mylan*, WL 784989, at *6. When he considered the low-ABUK patent claims, Judge Stein determined that "the 8α-derived limitation of the asserted product claims [would be] disregarded as a process limitation" that was immaterial to obviousness. *Teva*, 994 F. Supp. 2d at 405.[10] The *Teva* court thus only actually adjudicated the validity of the patents claiming "low-ABUK oxycodone API product." *Id.* at 403.

Accordingly, the proper comparison can be summarized by the chart below:

[10] "A court determines the obviousness of a product-by-process claim without reference to its process limitations." *Teva*, 994 F. Supp. 2d at 383–84; *accord Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012) ("In determining validity of a product-by-process claim, the focus is on the product and not the process of making it." (quoting *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed. Cir. 2009))).

<table>
<tr><th>Claim 1, ’933 patent (at issue)</th><th>Claim 1, ’072 patent (held invalid)</th></tr>
<tr><td>An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone.</td><td rowspan="3">An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, ~~wherein at least a portion of the 14:hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone.~~</td></tr>
<tr><th>Claim 16, ’933 patent (at issue)</th></tr>
<tr><td>An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, less than 5 ppm of codeinone, and less than 25 ppm of 14-hydroxycodeinone.</td></tr>
</table>

Claims 1 and 16 have three limitations that are not present in claim 1 of the ’072 patent: the 8α limitation, the 95% limitation, and (as to claim 16) the 5 ppm of codeinone limitation. All three limitations are mandatory. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (defining “comprising” as “a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim”).

Collegium contends that despite the surface differences between the product claims in this case and the prior litigation, issue preclusion should apply because those differences do not materially alter the validity analysis.

(1) <u>The 8α Limitation</u>

The Court will first take up the 8α limitation. Collegium first contends that issue preclusion should apply under the doctrine of inherency, because 8α was “necessarily present” in claim 1 of the ’072 patent. (Def. Summ. Judg. Br. at 17). “It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it.” *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). According to the doctrine, “the discovery of a previously unappreciated property of a

prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *see Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012) (rejecting idea that formulation could "become patentable merely by testing and claiming an inherent property").

But, as the *Mylan* court noted, the inherency doctrine applies when a claim is compared to the prior art. *Mylan* at *8. It is far from clear that the low-ABUK patents are prior art references with respect to the '933 patent. *See Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1281 (Fed. Cir. 1992) ("Our precedent makes clear that the *disclosure* of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, *even where the disclosure is found in the claims*."). And even if the doctrine is applicable, the Court also agrees with the *Mylan* court that there appear to be unresolved issues of material fact precluding summary judgment as to that issue. *Mylan* at *8. In short, like the *Mylan* court, the Court declines to find that Purdue is estopped from litigating the validity of the '933 patent by application of the inherency doctrine.

The question, then, is whether the differences between the claims here and the claims adjudicated in *Teva* are material to the question of validity. *See Ohio Willow Wood Co.*, 735 F.3d at 1342; *Soverain Software LLC*, 778 F.3d at 1319.

Collegium relies principally on *Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955 (Fed. Cir. 2017), in support of its argument that there are no material differences between the claims. In *Allergan*, the Federal Circuit affirmed the district court's application of issue preclusion to claims relating to a topical solution for increasing eyelash growth and darkness. *Allergan, Inc.*, 681 F. App'x at 959–62. Previously, other patent claims from the same patent family had been

found invalid on obviousness grounds. *See id.* at 957–58. Allergan argued that the prior cases had dealt with "whether it would have been obvious to use [the drug] to increase eyelash growth, not eyelash darkness," and thus that issue preclusion was inapplicable. *Id.* at 960. But the Federal Circuit determined that "the darkness limitation claimed in the Asserted Claims . . . was also disputed in all three prior litigations as one of many attributes flowing from the use of the claimed . . . solution." *Id.* The eyelash-darkness issue had been a matter of dispute for claim construction in the earlier litigation, as well. *Id.* Based on the fact that the asserted "novel" claim limitation of eyelash darkness had already been adjudicated, the Federal Circuit found that "the Asserted Claims are substantially similar to the invalidated claims . . . and that any differences between the claims do not materially alter the question of invalidity." *Id.* at 960–61.

Here, however, Judge Stein's ultimate conclusion of invalidity expressly disregarded the 8α process limitation. *Allergan* is therefore not directly on point. Nor has Collegium cited to any other authority that directly supports the application of issue preclusion here. Under the circumstances, the Court is reluctant to find that issue preclusion applies based solely on a claim-by-claim comparison.

Nonetheless, some troubling issues remain. This case involves a question of issue preclusion, not claim preclusion. Under traditional principles of issue preclusion, a party may be bound not simply by the ultimate conclusion of the prior court, but by any subsidiary factual determinations that were actually litigated and essential to the judgment. *See Rodríguez-García*, 610 F.3d at 770.

Here, a variety of factual questions were actually litigated in the *Teva* case; indeed, the bench trial lasted twenty days. In the process of rendering his decision that the relevant claims were invalid as obvious, Judge Stein made the following factual findings, among others:

- that 14-hydroxy is a potentially toxic impurity (994 F. Supp. 2d at 376, 385);
- that 8α is also an impurity (*id.* at 386);
- that 8α imparts no significance to the structure of 14-hydroxy (*id.* at 413);
- that 8α imparts no distinguishing characteristics to oxycodone (*id.*); and
- that 8α imparts no significance to the product claimed by the [low-ABUK] patents (*id.*).

If those findings are binding on Purdue, it is difficult to see how the 8α limitation would be material, or otherwise have any legal significance. Put another way, if a patent for an oxycodone composition with less than 25 ppm 14-hydroxy is invalid as obvious, it seems that a patent for the same product, with a meaningless impurity included, should likewise be invalid.

There is no question that Purdue had a fair opportunity to litigate those issues, or that the *Teva* case resulted in a valid and binding final judgment. The critical question therefore seems to be whether the factual findings concerning 8α were essential to the *Teva* judgment. The answer to that question is unclear. On the one hand, Judge Stein expressly ruled that he would disregard the 8α limitation in the low-ABUK patents, because his decision concerned only the product, not the process. But Purdue itself contended that its discovery of 8α, and the consequences of that finding, were the central issues in the case. *See, e.g., Purdue*, 811 F.3d at 1352 ("Purdue contends that the court failed to properly credit the discovery of 8α as the core of the claimed inventions"). And if none of the factual issues concerning 8α were essential to the judgment, it is at least noteworthy that so much trial time was consumed addressing those very issues.

However, the parties have not briefed the issue of whether any specific subsidiary factual findings made by the *Teva* court were necessary to the judgment, and therefore should have preclusive effect. And it is certainly possible that the proper analytical approach is not to employ

principles of issue preclusion, but rather a traditional summary judgment approach—that is, to consider whether there is a material dispute as to the significance of 8α. Judge Stein found that "the evidence overwhelmingly proved" that 8α had no significance in the final product. Perhaps there is no material evidence to the contrary, and perhaps a finding of obviousness would result from such a finding.

Under the circumstances, this Court will not resolve those questions here. It does appear, however, that the materiality of the 8α limitation in the product claims is very much in doubt, and therefore casts doubt on the validity of claims 1 and 16.

(2) The 95% Limitation

Both claims 1 and 16 further recite that the claimed products include "at least 95% oxycodone hydrochloride." ('933 patent col. 34 ll. 27–28, col. 35 ll. 13–14). The obviousness of that limitation was not decided or discussed in the *Teva* case. *See Mylan*, 2017 WL 784989, at *8–9 (noting that *Teva* "does not discuss the percentages of oxycodone in the prior art").

Collegium again contends that issue preclusion should apply, based on the doctrine of inherency. For reasons similar to those set forth above, the Court cannot determine whether the doctrine should apply under the present circumstances. Collegium also focuses on a statement in the '072 patent's specification that "[p]referably, the oxycodone hydrochloride preparation . . . contains at least 95% oxycodone hydrochloride," to argue that the low-ABUK patents disclosed a formulation with at least 95% oxycodone hydrochloride. ('072 patent, col. 5 l. 65–col. 6 l. 1). But that formulation was not necessarily present in the '072 patent or its claims; it was only "preferably" present. A preferred embodiment in a specification cannot be used to impose a claim limitation not otherwise present.

Nonetheless, there is substantial doubt as to whether the 95% limitation has any real

significance, and if it does whether the limitation would have been obvious to a person of skill in the art. Again, the resolution of those issues will await another day. But on the present record, the Court will not grant summary judgment as to the 95% limitation on the basis of issue preclusion.

(3) The 5 ppm Codeinone Limitation

Claim 16 contains the additional limitation that the composition comprises "less than 5 ppm of codeinone." Again, that limitation was not decided or discussed in *Teva*. *See Mylan*, 2017 WL 784989, at *9. Because it was not adjudicated in *Teva*, the Court cannot ascertain on the present record whether there is any material difference between those claims and claim 16.[11] Summary judgment will therefore be denied as to that limitation.

Accordingly, summary judgment will not be granted based on issue preclusion as to claims 1 and 16.

b. Claims 2, 3, 4, and 17

Because they are dependent from claims 1 and 16, the Court will also deny summary judgment on the basis of issue preclusion as to claims 2, 3, 4, and 17 of the '933 patent.

c. Claims 10 and 14

The principal issue as to claims 10 and 14 of the '933 patent is whether those are process claims (in which case issue preclusion is not applicable) or product-by-process claims (in which case it may be). The two claims are as follows:

[11] The specification of the '072 patent states that "[t]he process of the present invention also may result in the reduction of . . . codeinone." ('072 patent, col. 6 ll. 46–49). The phrase "may result" does not have the same meaning as "will necessarily result." *See In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981) (stating that "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient" to establish inherency (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939))).

Claim 10
A process for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.
Claim 14
The process of claim 10, wherein the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone is formed by hydrogenation.

Collegium contends that claims 10 and 14 are both product-by-process claims, because they define the product in terms of the process by which it is made. According to Collegium, the product claimed in claim 10 is "oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone." Because the court in *Teva* determined that a claim reciting an "oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone" was obvious and therefore invalid, Collegium argues that Purdue should therefore be precluded from relitigating the validity of the product claim.

Purdue, in turn, contends that claims 10 and 14 are process claims. The *Teva* court did not consider any process limitations in its decision because the asserted claims were product-by-process claims. *See Teva*, 994 F. Supp. 2d at 403. Purdue thus reasons that claim 10's process, which recites removing 8α, presents a new issue that would materially alter the validity analysis. The Court agrees with Purdue and finds that the application of issue preclusion is not appropriate.

Claim construction is a question of law. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) ("[T]he construction of a patent . . . is exclusively within the province of the court."). In the patent statute, the term "process" is defined as a "process, art or method." 35 U.S.C. § 100(b). More specifically, a process is "an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Gottschalk v. Benson*,

409 U.S. 63, 70 (1972) (quoting *Cochrane v. Deener*, 94 U.S. 780, 780 (1876)). Accordingly, process claims "consist[] of a series of acts or steps." *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002). A product-by-process claim, on the other hand, is focused on the product, defining it at least in part through the method by which it is made. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006) ("Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process.").

Claim 10 recites a series of steps, which include "removing 8α . . . from an oxycodone base composition" and "converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone." ('933 patent col. 34 ll. 54–58). Its language follows the same pattern as the independent claim adjudicated in *Chapman v. Casner*, 315 F. App'x 294 (Fed. Cir. 2009), which came from a patent from the same family as the low-ABUK patents. *See Teva*, 994 F. Supp. 2d at 388. The patent in *Chapman* claimed "[a] process for preparing oxycodone or an oxycodone salt," followed by the method's specific steps. *Chapman*, 315 F. App'x at 295. In affirming *Teva*, the Federal Circuit explained that the *Chapman* claim had been a process claim. *See Purdue*, 811 F.3d at 1349 (drawing contrast between process claim in *Chapman* and low-ABUK patents' claims). Claim 10 essentially mirrors that process-claim language. (*See* '933 patent col. 34 ll. 52–58).

This Court already implicitly construed claim 10 as a process claim in its memorandum and order on claim construction. (*See* Mem. & Order on Claim Construction at 18–19 (referring to "claimed process" in construing specific disputed claim terms)). The Court now makes that construction explicit and construes claims 10 and 14 as process claims.

The Court must next determine whether the differences between claims 10 and 14 and the

claims adjudicated in *Teva* would materially affect the validity analysis. *See Ohio Willow Wood Co.*, 735 F.3d at 1342. While the *Teva* court held that the low-ABUK patents were invalid as obvious, it found that "8α was unknown in the prior art: its very existence was unexpected." *Teva*, 994 F. Supp. 2d at 401. Unlike the low-ABUK patents and the '933 patent in the same family, "the prior art did not disclose the existence of 8α or teach that it converts to 14-hydroxy." *Id.* at 397. The presence of 8α in a process claim could therefore render the claim nonobvious. *See id.* at 407.

Under the circumstances, the step of "removing 8α" may materially affect the '933 patent's validity analysis. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (listing factors of obviousness analysis). At the very least, viewing the facts in the light most favorable to the non-moving party, Purdue has raised a disputed issue of material fact as to this point. Accordingly, Collegium will not be granted judgment as a matter of law as to claims 10 and 14 on the basis of issue preclusion.

B. <u>The '933 Patent: Non-Infringement</u>

Collegium also contends that it is entitled to summary judgment of non-infringement on the '933 patent. Collegium maintains that the doctrine of prosecution history estoppel and the Federal Circuit's opinion in *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356 (Fed. Cir. 2012), preclude Purdue as a matter of law from claiming that oxycodone myristate is the equivalent of oxycodone hydrochloride. Collegium further contends that XTAMPZA ER does not infringe under the doctrine of equivalents because oxycodone myristate does not perform the same function as oxycodone hydrochloride.

1. Doctrine of Equivalents

a. Limitations on Doctrine of Equivalents

Collegium first contends that Purdue's claim is barred by the doctrine of prosecution history estoppel. It contends that during prosecution of the application that would become the '072 patent, "Purdue specifically distinguished the [hydrochloride] form of oxycodone over other forms of oxycodone." (Def. Summ. Judg. Br. at 31). According to Collegium, having made that distinction to overcome a PTO rejection, Purdue thereby disclaimed all forms of oxycodone other than oxycodone hydrochloride.

Argument-based estoppel will only be applied when the prosecution history "evince[s] a clear and unmistakable surrender of subject matter." *Conoco, Inc.*, 460 F.3d at 1364 (quoting *Deering Precision*, 347 F.3d at 1326). "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.* (quoting *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1457 (Fed. Cir. 1998), *abrogated on other grounds*, 135 S. Ct. 831 (2015)).

During the prosecution, the examiner initially rejected all of the '072 patent application's claims in light of U.S. Patent No. 6,177,567 ("Chiu"). (*See* Def. Ex. 19 at 2–3). Specifically, the examiner stated that "it would have been obvious to one skilled in the art to prepare the instant Oxycodone hydrochloride composition having less impurities with different levels of [14-hydroxy] since Chiu teaches determining levels of [14-hydroxy] by HPLC during preparation of Oxycodone or its salt." (Def. Ex. 19 at 3). In response to the examiner's rejection of the '072 patent application claims, Purdue wrote:

> Independent claim 71 is directed to a pharmaceutical composition comprising oxycodone **hydrochloride** and [14-hydroxy]. The [14-hydroxy] is present in the amount of less than 25 ppm. Applicants respectfully submit that the Chiu patent does not describe determining the level of [14-hydroxy] during preparation of the

> **oxycodone hydrochloride salt**. Instead, the Chiu patent only describes determining the level of [14-hydroxy] during preparation of the **oxycodone free base**.

(Def. Ex. 20 at 5). Collegium relies on that language to argue that "Purdue distinguished oxycodone [hydrochloride] salts from other forms of oxycodone (i.e.[,] the oxycodone myristate in Collegium's formulation)" and is therefore estopped from claiming that oxycodone myristate is the equivalent of oxycodone hydrochloride. (Def. Summ. Judg. Br. at 32).

Based on that language, Purdue may well have disclaimed products including oxycodone free base during prosecution. But it does not follow that Purdue necessarily surrendered *all* forms of oxycodone other than oxycodone hydrochloride. At a minimum, Purdue's response to the examiner did not clearly disclaim all other forms of oxycodone, including oxycodone myristate. *See Conoco, Inc.*, 460 F.3d at 1364 (holding that applicant's argument that "a fatty acid wax was not the same as a metal stearate" clearly disavowed metal stearates as equivalents, but did not surrender all fatty acid wax equivalents).

Collegium also asserts that this case is analogous to *Wrigley*, 683 F.3d at 1356, which articulates a limitation on the doctrine of equivalents that is distinct from prosecution history estoppel. The doctrine of equivalents cannot be used to expand "manifestly limited claims." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997). Thus, narrowly disclosing and claiming in a patent will curtail the scope of possible equivalent elements. *See Wrigley*, 683 F.3d at 1365–66; *Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n*, 109 F.3d 726, 732 (Fed. Cir. 1997).

In *Wrigley*, the Federal Circuit upheld the district court's decision on summary judgment that Cadbury could not assert the doctrine of equivalents in a dispute over cooling chewing gum patents. *See Wrigley*, 683 F.3d at 1366. Cadbury had claimed a "chewing gum

composition . . . comprising a gum base, a sweetener and a cooling composition comprising menthol and an N-substituted-p-methane carboxamide of [a specific formula]." *Id.* at 1358. Wrigley's accused cooling composition comprised menthol and "WS-23," which is a carboxamide, but not an N-substituted-p-methane carboxamide. *Id.* at 1359. In holding that Cadbury could not recapture WS-23 as an equivalent, the Federal Circuit noted that the patent narrowly disclosed N-substituted-p-methane carboxamides specifically, rather than carboxamides generally. *Id.* at 1365. That narrow focus was demonstrated, among other ways, in the "Summary of the Invention" section of Cadbury's patent, which stated: "[A]pplicants have unexpectedly found that N-substituted-p-methane carboxamides when used in combination with menthol in specific amounts results in an unexpected heightened cooling sensation in edible products." *Id.* at 1365–66. Moreover, the specification noted that N-substituted-p-methane carboxamides were structurally similar to menthol, and WS-23 was not similar to menthol in that way. *Id.* at 1366. Based on these "expressions of manifest exclusion or restriction," *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002), the court found that the doctrine of equivalents did not extend to WS-23.

In its opinion, the Federal Circuit also distinguished *Abraxis Bioscience, Inc. v. Mayne Pharma Inc.*, 467 F.3d 1370 (Fed. Cir. 2006). 683 F.3d at 1366. In *Abraxis*, the issue was whether one compound ("X") could be considered the equivalent of another, structurally analogous compound ("Y"). The patentee had narrowly claimed compound X. The *Wrigley* court noted that the court "rejected the argument that such narrow claiming precluded the patentee from arguing that [compound Y] was an equivalent of [compound X]," and "[i]n so finding, we relied on the fact that it was unknown at the time of invention that the properties of [compound Y] made it a suitable substitute for [compound X] in the claimed invention." *Id.* It

went on to hold that the facts in *Wrigley* supported "the opposite inference," because the inventors had been specifically informed that "the two compounds were appropriate for the same uses." *Id.* "Thus, the inventors were on notice of the potential interchangeability of [the two cooling compounds], yet they drafted the claims of the . . . patent narrowly," to include one compound but not the other. *Id.*

Collegium maintains that Purdue's argument that oxycodone myristate is the equivalent of oxycodone hydrochloride is foreclosed under *Wrigley*, because the '933 patent's claims and specification focus specifically on oxycodone hydrochloride. Furthermore, Collegium argues that the claims "are even more narrow," claiming only the subset of oxycodone hydrochloride "that contain[s] a reduced amount of [14-hydroxy]." (Def. Summ. Judg. Br. at 34). Purdue counters that *Wrigley* is inapplicable because "the focus of the '933 patent is not on any particular oxycodone salt, but rather an oxycodone composition with reduced levels of [14-hydroxy] and 8α." (Pl. Summ. Judg. Opp. at 31).

Although it is perhaps a close call, this Court will not apply *Wrigley* to preclude Purdue's ability to argue that oxycodone myristate is equivalent to oxycodone hydrochloride. It is true that throughout the specifications and claims in the '933 patent, Purdue stated that the invention was (1) an oxycodone hydrochloride composition having low levels of 14-hydroxy and 8α and (2) the process for preparing that particular composition. (*See, e.g.*, '933 patent col. 2 ll. 30–46, col. 6 ll. 34–50, col. 34 ll. 26–30). The "Background of the Invention" section specifically states that the patent was responding to the "continuing need in the art to provide an oxycodone hydrochloride composition that contains reduced amounts of [14-hydroxy]." (*Id.* col. 2 ll. 20–23). Thus, as in *Wrigley*, the disclosure of the '933 patent "focuses narrowly on [oxycodone hydrochloride salt], and not on [oxycodone salts] generally." *Wrigley*, 683 F.3d at 1365. But

here, unlike in *Wrigley*, the record evidence does not support the inference that the '933 patent's inventors were explicitly aware of the alleged interchangeability of oxycodone myristate when they chose to narrowly claim only oxycodone hydrochloride. Under the circumstances, the Court will not grant summary judgment based on the principles of *Wrigley*.

b. Function-Way-Result Analysis

"[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson Co.*, 520 U.S. at 29. When applying the function-way-result test, a court therefore must analyze the precise role of a missing claim element. *See id.* at 40; *see also Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1296 (Fed. Cir. 2009) ("Infringement analysis under the doctrine of equivalents proceeds element-by-element.").

The disagreement between Collegium and Purdue on the doctrine of equivalents issue boils down to a dispute about the relevant points of comparison. In its argument that XTAMPZA ER cannot infringe the '933 patent under the doctrine of equivalents, Collegium compares the functions of "hydrochloride" or "hydrochloric acid" in Purdue's product and "myristic acid" in its own product. (*See* Def. Summ. Judg. Br. at 29–31; Def. Summ. Judg. Reply at 6–7). Collegium maintains that myristic acid functions "to lock oxycodone up in wax so that it is not accessible to an abuser." (Def. Summ. Judg. Br. at 31).

There is undisputed record evidence supporting that claimed function of myristic acid. First, it is undisputed that myristic acid functions as an "API solubilizer in formulation." (Pl. Response ¶ 69; Def. Ex. 9 at COLL0001212, Table 10). Similarly, it is undisputed that myristic acid works to "solubilize the oxycodone base drug substance in the microsphere formulation." (Pl. Response ¶ 24; Def. Ex. 9 at COLL0001212). Based on that evidence, Collegium asks this Court to find that "myristic acid . . . functions to solubilize oxycodone in the wax matrix and

hydrochloric acid . . . functions to make oxycodone bioavailable," and are therefore not equivalents. (Def. Summ. Judg. Reply at 7).

Purdue, on the other hand, maintains that the correct comparison for the function-way-result test does not involve myristic acid at all. (*See* Pl. Summ. Judg. Opp. at 28). Purdue argues that "[t]he claim element that is literally missing from [XTAMPZA ER], and for which the doctrine of equivalents is relevant, is *oxycodone hydrochloride*, not 'hydrochloride.' The equivalent element is *oxycodone myristate*, not myristic acid." (*Id.*). At least for summary judgment purposes, the Court agrees with Purdue's assessment. Nowhere in the '933 patent's claims does Purdue claim "hydrochloride" or "hydrochloric acid"; rather, the specific claim element is an "oxycodone hydrochloride composition." (*E.g.*, '933 patent col. 34 l. 27). Thus, the oxycodone hydrochloride salt composition is the missing element in XTAMPZA ER, and oxycodone myristate salt is the appropriate comparator under the doctrine of equivalents. In its reply brief, Collegium even seems to concede this point. (*See* Def. Summ. Judg. Reply at 6 ("It is undisputed that the pharmaceutical salt in [XTAMPZA ER] is oxycodone myristate, not the oxycodone HCl salt claimed in the '933 patent.")).

The Court therefore must determine whether the alleged equivalency of oxycodone myristate and oxycodone hydrochloride is a question for a jury. Stripping away the evidence concerning myristic acid, Collegium only presents one argument that oxycodone myristate and oxycodone hydrochloride are not equivalents. It argues that while oxycodone hydrochloride is the API in OxyContin, oxycodone myristate does not perform the API function in XTAMPZA ER. (*See* Def. Summ. Judg. Br. at 29; Def. Ex. 26 at P3430662; Def. Ex. 9 at COLL0001212, Table 10). Rather, according to Collegium, the API in XTAMPZA ER is oxycodone base, not oxycodone salt. (*See* Def. Ex. 9 at COLL0001212, Table 10). But in its Rule 56.1 Reply

Statement, Collegium seems to refute its own argument and acknowledge that oxycodone myristate is, in fact, the API. (*See* Def. Reply ¶¶ 131, 134). Purdue also refers to Collegium's own statement to the SEC and the FDA that XTAMPZA ER "has the same active ingredient as OxyContin." (Pl. Ex. 11 at 4).

Purdue has also submitted expert testimony from Dr. Stephen Byrn. Dr. Byrn's affidavit states that "[t]he function of both the claimed oxycodone hydrochloride and Collegium's oxycodone myristate is to provide oxycodone, which provides pain relief to a patient." (Byrn Decl. ¶ 15). He opines that by stating that "[o]xycodone is present as myristate salt in the XTAMPZA ER formulation," (Def. Ex. 27 at COLL0023272), "Collegium is acknowledging that the role of the oxycodone salt is to deliver the oxycodone," (Byrn Decl. ¶ 17).

While the Court agrees that this articulation of the function of the two salts may be overly broad, Collegium has provided insufficient evidence as to the function of oxycodone myristate—as opposed to myristic acid—to refute Purdue's theory. Collegium only asserts that oxycodone myristate is "almost insoluble in water," which Purdue disputes, and that oxycodone hydrochloride is highly water soluble. (Def. SOF ¶¶ 71–72; Pl. Response ¶¶ 71–72). What significance, if any, these facts have on the function of the two salts is not made clear.

It appears that Purdue has presented a genuine issue of disputed material fact as to whether oxycodone myristate performs substantially the same function as oxycodone hydrochloride, and that accordingly summary judgment is inappropriate. The Court therefore need not consider whether there are disputed issues concerning the "way" or "result" aspects of the equivalency test.

2. Direct and Indirect Infringement of Process Claims 10 and 14

Collegium argues that it cannot infringe process claims 10 and 14 because (1) it does not

perform all of the claimed steps itself and (2) it does not direct or control the companies that do perform the claimed steps. Purdue, however, asserts that Collegium directs or controls the manufacturing processes of Noramco and Patheon that infringe claims 10 and 14.

It is undisputed that Noramco manufactures, pursuant to contract, oxycodone base for Collegium's oxycodone myristate compositions. (*See* Def. Reply ¶¶ 124–25). It is also undisputed that Patheon manufactures XTAMPZA ER for Collegium, converting oxycodone base to oxycodone myristate. (*See id.* ¶¶ 129–31). Accordingly, it would be premature at best to grant Collegium summary judgment of non-infringement of claims 10 and 14 based on the record before the Court. *See Akamai Techs., Inc.*, 797 F.3d at 1023 (stating that "an actor is liable for infringement under § 271(a) if it . . . contracts with another to perform one or more steps of a claimed method"). Thus, the Court will deny summary judgment of non-infringement with respect to claims 10 and 14.

C. The '497 Patent and the '717 Patent: Non-Infringement

Finally, Collegium argues that it is entitled to summary judgment of non-infringement of the '497 patent and the '717 patent because the myristic acid used in XTAMPZA ER is not an "irritant." The resolution of that issue turns on the Court's previous construction of the term "irritant."

As noted, Collegium uses myristic acid in XTAMPZA ER to dissolve oxycodone base in wax. Although Purdue does not dispute that myristic acid has such a purpose, it contends that myristic acid was also included in XTAMPZA ER to act as "an abuse-deterring irritant." (Pl. Response ¶¶ 23–24). Purdue points to the high ratio of myristic acid to oxycodone base in the microspheres, as well as the fact that any excess myristic acid remains in XTAMPZA ER in its acid form, to support its claim. (*Id.* ¶¶ 149–50, 153). According to Purdue, the molar ratio of

myristic acid to oxycodone base in XTAMPZA ER is 6:1, while Purdue asserts that the molar ratio of a complex of oxycodone base and myristic acid would be 1:1. (*See id.* ¶ 23; Byrn Decl. ¶ 28). This, Purdue contends, is evidence that the extra myristic acid functions solely as an irritant. For additional support, Purdue cites results of abuse-potential studies conducted by Collegium, which state effects such as "irritation, burning, and facial pain" after snorting "may be desirable for this type of product as this may serve as a nuisance to an abuser who attempts to snort the drug." (Pl. Response ¶ 163).

Collegium disputes Purdue's assertions that "[t]he amount of myristic acid in [XTAMPZA ER] is more myristic acid than necessary for all of the oxycodone base to be part of an oxycodone myristate salt." (Pl. Response ¶ 151; Def. Reply ¶ 151). It contends that all of the myristic acid is necessary to solubilize oxycodone and drive salt formation. (*See* Def. Summ. Judg. Reply at 11–12; Def. Ex. 37 at COLL0001253). Its NDA for XTAMPZA ER specifically states that excess myristic acid is necessary to ensure that enough oxycodone myristate is formed and to reduce the concentration of free oxycodone base. *See* Suppl. Ex. 37 at COLL0001253 ("[E]xcess free acid . . . serves to drive salt formation, [thereby] reducing the free base concentration in the system and preventing its precipitation."). It also reported that it attempted to make the API using a 1:1 ratio, but it failed. *Id.* at COLL0001252 ("During early stage development . . . , [attempts at] combining the free acid and the free base of oxycodone at a molar ratio of 1:1 were unsuccessful."). Ultimately, it concluded that the lowest ratio of myristic acid to oxycodone that was capable of completely dissolving the oxycodone base was 1:5.6. *Id.* at COLL0001251.

With respect to the abuse-potential studies, Collegium explains that its NDA stated that irritation after snorting was "likely caused by particle size and lack of solubility of the wax

microspheres." (Def. Reply ¶ 163; Def. SOF ¶ 90). Collegium also denies that myristic acid was included for any purpose other than solubilizing oxycodone in the wax matrix. (*See, e.g.*, Def. Reply ¶ 155; Def. SOF ¶ 84).

In its summary judgment and claim construction briefing, Collegium advocated for "irritant" to be construed as meaning "a compound used to impart an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention," based on the common specification's definition. Collegium does not dispute that myristic acid has some irritating qualities, at least under exaggerated exposure conditions. And while it may downplay the significance of the tests it conducted, Collegium does not dispute that an *in vitro* volatilization study and an intranasal abuse study produced results that showed XTAMPZA ER may cause irritation when abused. (*See* Def. SOF ¶¶ 85–87, 90; Def. Ex. 6 at COLL0013058–59, COLL0013077–78). Collegium, however, maintains that Purdue can point to no evidence that Collegium uses myristic acid for the purposes of imparting an irritating or burning sensation to someone abusing the drug.

The issue, however, is not Collegium's intent. In construing the term "irritant" in the two patents, the Court steered clear of assigning the disputed claim term "a meaning . . . that depends on the state of mind of the accused infringer." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1353 (Fed. Cir. 2001). Rejecting Collegium's proposal, the Court construed "irritant" to mean "a compound that imparts an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention." (Mem. & Order on Claim Construction at 15).

But the Court limited its construction based on the plain language of Purdue's claim:

> Thus, by its plain terms, the claim is for a product with four components (or types of components)—drug, a release carrier, an irritant, and an excipient (A, B, C, and

> D). A product with only three components (a drug, a release carrier, and an excipient, or A, B, and D) would not appear to infringe, even if one or more of those components happens (as an unintentional consequence) to impart an irritating sensation upon tampering. In other words, if a drug contains a pharmaceutical excipient (component D) with an excipient function (function Z) that also happens to irritate when the product is abused, that excipient would not qualify as an "irritant" under the claim, because excipients and irritants are different components, according to its plain language.

(*Id.* at 14). The Court also looked to the prosecution history to find that "Purdue clearly and unambiguously expressed surrender of items that overlap—for example, as both a pharmaceutical excipient and an irritant." (*Id.*).

Here, Purdue has conceded that at least some of the myristic acid in XTAMPZA ER has an excipient function. (*See* Pl. Response ¶ 23 (agreeing that "one alleged purpose for including myristic acid in Xtampza is that it is capable of dissolving oxycodone base in the wax matrix"); Mem. & Order on Claim Construction at 11 n.2 (noting that solvents are an example of an excipient)). Substances with overlapping functions do not infringe on the asserted claims of the '497 and '717 patents because the language of the claims prohibit, and Purdue expressly surrendered, that interpretation. But one way to interpret Purdue's argument is that the same substance may have parallel, non-overlapping functions. Its argument suggests that XTAMPZA ER contains both an excipient (myristic acid) and an irritant (excess myristic acid, not necessary to solubize oxycodone)—in other words, that the product contains a quantity of myristic acid serving an excipient function and a separate quantity of myristic acid serving an irritant function (but not an excipient function).

In theory, such an argument might succeed, assuming that the excess myristic acid had no function other than being an irritant. But Collegium has put forth evidence that what appears to be "excess myristic acid" is in fact an excipient and performs a necessary function. Purdue has not rebutted that evidence with anything other than speculation and argument. Again, Purdue

claimed a composition with a separate "irritant" component. It does not (and likely could not) claim every composition that happened to have an irritating quality under some set of circumstances, whether or not the irritant was a separate component. Accordingly, and under the circumstances, the Court will grant summary judgment as to non-infringement of the'497 and '717 patents.

IV. Conclusion

For the foregoing reasons, the motion for summary judgment of Collegium Pharmaceutical, Inc. is GRANTED in part and DENIED in part. Specifically, summary judgment is granted to defendant on all claims of infringement of U.S. Patent Nos. 8,652,497 and 9,155,717, and is otherwise denied.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: September 28, 2018